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December 31, 2019

VIA ECF

Honorable Freda L. Wolfson
United States District Court- District of NJ
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street, Court Room 5E
Trenton, NJ 08608

**Re: In re: Johnson & Johnson Talcum Powder Products
Marketing, Sales Practices and Products Liability Litigation
MDL No. 2738**

Dear Chief Judge Wolfson:

I am writing in response to the PSC's December 24 letter identifying four publications that purportedly "support" plaintiffs' experts' general causation opinions. This letter (along with plaintiffs' latest round of repetitive discovery requests, served yesterday) appears calculated to delay a ruling on defendants' *Daubert* motions, which have now been fully briefed and argued for five months. As explained below, however, the papers that the PSC identifies do not bolster the reliability of plaintiffs' experts' opinions and should be disregarded in assessing the parties' *Daubert* motions.

First, and most fundamentally, the pending *Daubert* motions address whether the proffered experts followed sufficiently reliable methods to satisfy the requirements of *Daubert* and Fed. R. Evid. 702. These papers, ***on which none of the challenged experts relied***, cannot possibly shed any light on that question because they say nothing about these experts' ***methodologies***. Rather, they are simply studies identified by plaintiffs' counsel that supposedly support the experts' ***conclusions***. *See, e.g., In re Human Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 655, 667 (D.N.J. 2008) (if an expert fails to adequately support his or her opinion, "counsel cannot fill in the gaps"); *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 671 (6th Cir. 2010) (rejecting attempt to salvage expert's unreliable methods by reference

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to bases on which expert's opinions did not rest); *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 407 (S.D.N.Y. 2005) ("The subject of this motion is the proposed testimony of experts, not the theories of lawyers."). For this reason alone, the PSC's letter has no relevance to this Court's *Daubert* analysis.

Second, and in any event, even if plaintiffs' experts had relied on these publications, they would not support either the witnesses' methodologies or their conclusions, for the following reasons:

- Steffen, et al., *Serous Ovarian Cancer Caused By Exposure To Asbestos In Cosmetic Talc – A Case Series*, J. Occupational & Environ. Medicine (published ahead of print) (attached as Ex. A to PSC's Ltr.). This article, co-authored by three plaintiffs' experts and paid for by plaintiffs' counsel (*see id.* at 2-3), is a case series reporting purported findings of talc or asbestos in the tissue of 10 talcum powder plaintiffs. The case series lacked any control group of tissue from unexposed women, and as such, it cannot support any inference that the particles identified came from perineal talc dusting. Nor does it say anything about the cause of these plaintiffs' diseases. Such a study is plainly insufficient to support plaintiffs' causal theory. *See, e.g., Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1453 (D.V.I. 1994) ("one cannot draw causal conclusions from" case reports), *aff'd*, 46 F.3d 1120 (table), 1994 WL 16973481 (3d Cir. 1994); *Siharath v. Sandoz Pharm. Corp.*, 131 F. Supp. 2d 1347, 1361-62 (N.D. Ga. 2001) (collecting cases for the same proposition). The lack of any control group is especially significant here, since previous literature has found talc in the tissue of women without any history of perineal talc exposure as well as women who have used talc in their perineal area. *See Heller, et al., The Relationship Between Perineal Cosmetic Talc Usage and Ovarian Talc Particle Burden*, Am. J. Obstet Gynecol. 1507 (1996).
- O'Brien, et al., *Genital Powder Use & Risk Of Ovarian Cancer: A Pooled Analysis*, APSO Abstracts (2019) (attached as Ex. B to PSC's



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Ltr.). This is an abstract for a forthcoming article that has not yet been published. Therefore, neither defendants nor the Court can adequately review its methodology or evaluate its reliability. For example, while the abstract states that the authors adjusted for confounders, there is no indication of which confounders were considered or how they were controlled for. But even taken at face value, the abstract fails to support the PSC's position because it **does not** show a statistically significant association between perineal talc use and ovarian cancer among women generally – and its authors never claim that it does. Rather, it reports a self-described “weak” point estimate of 1.09 for all users, with a 95% confidence interval that includes 1 (1.00, 1.20) – meaning the results are not statistically significant. *Id.* at 2. And for long-term users, the point estimate is even lower at 1.04 (CI: 0.84-1.29). The authors conclude that they have identified a weak association only in women with patent reproductive tracts and with no clear differences among different subtypes, which does not support causation for all the reasons defendants' experts have previously explained.

- Mandarino, et al., *The Effect Of Talc Particles on Phagocytes In Co-Culture With Ovarian Cells*, 180 Environ. Research (forthcoming 2020) (attached as Ex. C to PSC's Ltr.). The PSC supposedly offers this study (also co-authored by one of plaintiffs' experts) to bolster the opinions of their biological mechanism expert, Dr. Saed. But no study could cure the manifold errors and irregularities defendants identified in Dr. Saed's work. In any event, the in vitro effects that Mandarino and his colleagues claimed to observe have **nothing to do with** the mechanism Dr. Saed proposes. Rather, Mandarino, et al. set out to determine whether “interaction with talc particles compromises” macrophages in **already-malignant cell lines** and “reduc[es] their anti-tumor abilities.” *Id.* at 1. In other words, the experiment investigated whether talc compromised the immune system's ability to fight tumors once they arise, not whether normal cells can transform into tumor cells in the first place. As the authors of the paper frankly conceded, “**we focused not on the process of carcinogenesis**, but rather on the [supposed] immunotoxic effect of talc.” *Id.* at 2



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(emphasis added); *see also id.* at 9 (“we did not investigate the [alleged] carcinogenic properties of talc per se”).¹ Moreover, even as to the issue studied, the authors stopped short of any claims of human significance, writing that “[f]urther research is needed to determine whether and to what extent the effect of talc on phagocytes exists in vivo, particularly in humans.” *Id.* at 10.

- McDonald, et al., *Migration of Talc From The Perineum To Multiple Pelvic Organ Sites: Five Case Studies With Correlative Light & Scanning Electron Microscopy*, 152 Am. J. Clinical Pathology 590 (2019) (attached as Ex. D to PSC’s Ltr.). This case series (also co-authored by some of plaintiffs’ experts) purported to find more significant talc burdens in tissue samples from five patients who had used talc perineally than in tissue samples from six patients who had not. But, as indicated above, courts strongly reject drawing any causal conclusions from case reports like this one. And this case report is especially suspect. It involved a tiny sample size – just five exposed cases. And while the authors purported to include a control sample, those tissues were not collected during the same timeframe or by the same investigators, and the supplies and techniques used to process them were not reported, *see id.* at 3-4, raising the possibility that collection and processing methods, rather than exposure, drove any differences in the quantity of talc observed.

In short, although research continues into talc-related matters (much of it funded by plaintiffs’ counsel), none of it supports a finding of biological plausibility, let alone causation. Nor does this research demonstrate in any way that plaintiffs’ experts’ opinions were based on reliable methodologies. Accordingly, plaintiffs’ latest submission should have no bearing on the

¹ To the extent the study can be read to have any relevance to Dr. Saed’s work at all, it casts doubt on it, since talc particles “did not significantly affect the numbers of [murine ovarian] cells after 72 h[ours],” Mandarino, et al. (2019), at 4; in other words, there was no cell proliferation.

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Court's *Daubert* analysis, and neither this submission nor plaintiffs' latest discovery requests should otherwise delay the Court's ruling.

Respectfully submitted,

/s/ Susan M. Sharko

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cc: All Counsel of Record (via ECF)